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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/148,012 09/04/98 KRIEGER

M MIT7150CIP(2

EXAMINER

HM12/0911

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LANDSMAN, R

ART UNIT

PAPER NUMBER

1647

DATE MAILED:

09/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/148,012

Applicant(s)

KRIEGER, MONTY

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 September 1998 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

1. Formal Matters

- A. Amendment A, filed 6/26/00, has been entered into the record.

2. Oath/Declaration

- A. The objection to the declaration has been withdrawn since the correction to the declaration regarding the address of Monty Krieger was made in ink and initialed.

3. Specification

- A. The objection to Figure 1 is maintained since, while Figure 1 recites parts (a)-(d) in lower case letters, the Brief Description of Drawings refers to these parts as 'A-D' in capital letters. Appropriate correction is required.

4. Claim Rejections - 35 USC § 112, first paragraph

- A. The rejection of claim 17 under 35 USC 112, first paragraph has been withdrawn since Applicants cancelled the claim.

5. Claim Rejections - 35 USC § 112, second paragraph

- A. The rejection of claim 17 under 35 USC 112, second paragraph has been withdrawn since Applicants cancelled the claim.

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6. Claim Rejections - 35 USC § 102

C. Claims 1-7, 15 and 16 remain rejected under 35 USC 102(a) as being unpatentable over Rigotti et al. for the reasons already of record on pages 4-5 of the Office Action dated 3/16/00. Applicant has amended claim 1 to recite that the method is to be used in a mammal in need of treatment by alteration of reproductive hormone levels by altering expression of or binding to cholesterol to tissues producing reproductive hormones. Applicant argues that the claim excludes treatment with estrogen. First, Applicant recites "a compound" in the claim, which encompasses estrogen, and is, therefore, arguing limitations that have not been recited in the claims. In addition, Rigotti et al. (page 183, right column, second paragraph) teach that hCG and other compounds also increase SR-BI expression and that SR-BI receptors are found in tissues producing reproductive hormones (ovary; page 183, column 1 under "Tissue-specific expression of scavenger receptor BI").

Applicant argues that none of the art cited by the Examiner discloses nor makes obvious the method of claim 1. Applicant also argues that only after Applicant observed the effect of knocking out SR-BI could one draw the corollary that this was a way to treat reproductive disorders. However, whether the exact mechanism was known or not at the time of the invention, the mechanism of action would be inherent to the claimed method.

B. Claims 1 and 8 remain rejected under 35 USC 102(a) as being unpatentable over Spona et al. for the reasons already of record on page 5 of the Office Action dated 3/16/00. Applicant has amended claim 1 to recite that the method is to be used in a mammal in need of treatment by alteration of reproductive hormone levels by altering expression of or binding to cholesterol to tissues producing reproductive hormones. Applicant argues that the claim excludes treatment with estrogen. First, Applicant recites "a compound" in the claim, which encompasses estrogen, and is, therefore, arguing limitations that have not been recited in the claims. Even though Applicant added the limitation that the method must occur in

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steroidogenic tissues producing reproductive hormones, Spona et al. still meet this limitation since it was noticed that there was an increase in ovarian activity and in the levels of various hormones involved in reproduction (Abstract). The limitation that the patient be in need of treatment by alteration of reproductive hormone levels is met by the reference since the study was done to test the effect of oral contraceptives, which would be needed by women desiring a means of birth control.

The reference is silent with regard to whether these compounds affect SR-BI expression, or SR-BI binding to lipoprotein in these tissues, or other limitations recited in the claims (especially claim 1). However, the U.S. Patent and Trademark Office does not have a laboratory to test this part of the claim. *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980) states that when a reference discloses all the limitations of a claim except a property or function, and the Examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention, he has the basis for shifting the burden of proof to the Applicant. See MPEP Sections 2112-2112.02.

C. Claims 1, 9, 12 and 13 remain rejected under 35 USC 102(a) as being unpatentable over Bajetta et al. for the reasons already of record on pages 5-6 of the Office Action dated 3/16/00. Applicant has amended claim 1 to recite that the method is to be used in a mammal in need of treatment by alteration of reproductive hormone levels by altering expression of or binding to cholesterol to tissues producing reproductive hormones. Applicant argues that the claim excludes treatment with estrogen. First, Applicant recites "a compound" in the claim, which encompasses estrogen, and is, therefore, arguing limitations that have not been recited in the claims. Applicants argue that only after the Applicant knocked out SR-BI expression could a corollary be made to SR-BI involvement in certain disorders. Bajetta et al. teach a method of modifying steroid production in a mammal in need of treatment by alteration of reproductive hormone levels since estrogen (produced in "reproductive tissues") is involved in the progression of breast cancer (page 145, paragraph 2 of the Introduction; also under "Patients and Methods"). Patients

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who have breast cancer would be in need of treatment by a method of modifying levels of, for example, estrogen as taught by Bajetta et al.

The reference is silent with regard to whether these compounds affect SR-BI expression, or SR-BI binding to lipoprotein in these tissues, or other limitations recited in the claims (especially claim 1). However, the U.S. Patent and Trademark Office does not have a laboratory to test this part of the claim. *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980) states that when a reference discloses all the limitations of a claim except a property or function, and the Examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention, he has the basis for shifting the burden of proof to the Applicant. See MPEP Sections 2112-2112.02.

D. Claims 1, 9, 12 and 14 remain rejected under 35 USC 102(a) as being unpatentable over Cirkel et al. for the reasons already of record on page 6 of the Office Action dated 3/16/00. Applicant has amended claim 1 to recite that the method is to be used in a mammal in need of treatment by alteration of reproductive hormone levels by altering expression of or binding to cholesterol to tissues producing reproductive hormones. Applicant argues that the claim excludes treatment with estrogen. First, Applicant recites "a compound" in the claim, which encompasses estrogen, and is, therefore, arguing limitations that have not been recited in the claims. Applicants also argue that only after the Applicant knocked out SR-BI expression could a corollary be made to SR-BI involvement in certain disorders. Cirkel teaches a method of modifying steroid production in a mammal in need of treatment by alteration of reproductive hormone levels in tissues producing reproductive hormones since the administration of danazol inhibits steroidogenesis in the gonads (page 93, first full paragraph). Therefore, danazol would be administered to patients in need of a treatment modifies reproductive hormone levels.

The reference is silent with regard to whether these compounds affect SR-BI expression, or SR-BI binding to lipoprotein in these tissues, or other limitations recited in the claims (especially claim 1).

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However, the U.S. Patent and Trademark Office does not have a laboratory to test this part of the claim. *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980) states that when a reference discloses all the limitations of a claim except a property or function, and the Examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention, he has the basis for shifting the burden of proof to the Applicant. See MPEP Sections 2112-2112.02.

E. Claims 1, 10 and 11 remain rejected under 35 USC 102(a) as being unpatentable over Whitcroft and Stevenson for the reasons already of record on page 6 of the Office Action dated 3/16/00. Applicant has amended claim 1 to recite that the method is to be used in a mammal in need of treatment by alteration of reproductive hormone levels by altering expression of or binding to cholesterol to tissues producing reproductive hormones. Applicant argues that the claim excludes treatment with estrogen. First, Applicant recites "a compound" in the claim, which encompasses estrogen, and is, therefore, arguing limitations that have not been recited in the claims. Applicants also argue that only after the Applicant knocked out SR-BI expression could a corollary be made to SR-BI involvement in certain disorders. Whitcroft and Stevenson teach a method of modifying steroid production in a mammal in need of treatment by alteration of reproductive hormone levels by altering expression of SR-BI in tissues producing reproductive hormones since the administration of the correct nutrients (i.e. compounds) would be expected to alter steroidogenesis in tissues producing reproductive hormones (page 15, column 2, fourth full paragraph). Therefore, various nutrients would be administered to patients in need of a treatment modifies reproductive hormone levels.

The reference is silent with regard to whether these compounds affect SR-BI expression, or SR-BI binding to lipoprotein in these tissues, or other limitations recited in the claims (especially claim 1). However, the U.S. Patent and Trademark Office does not have a laboratory to test this part of the claim. *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980) states that when a reference discloses all the

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limitations of a claim except a property or function, and the Examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention, he has the basis for shifting the burden of proof to the Applicant. See MPEP Sections 2112-2112.02.

New Rejections

1. Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for estrogen (Example 3 of the specification) and anti-SR-BI antibody (Example 8 of the specification), does not reasonably provide enablement for all compounds listed on page 11, lines 11-17 of the specification. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to a method of modifying steroid production in a mammal by administering a compound. However, the specification only provides guidance and working examples for estrogen and anti-SR-BI antibodies. There is no guidance or working example of the use of antisense oligonucleotides, ribozymes, all small organic molecules or soluble SR-BI proteins, or fragments thereof, etc.

Therefore, due to a lack of guidance and working examples as to which compounds of the ones listed on page 11, lines 11-17 of the specification would have the desired effect in the present invention as well as the unpredictability in the art as to knowing which compounds would produce the desired effect, the Examiner has determined that the Applicant is not enabled for all compounds encompassed by all of

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the groups of compounds listed on page 11, lines 11-17 of the specification and, therefore, that undue experimentation would be needed to practice the invention as claimed.

Advisory information

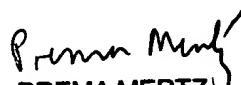
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
September 08, 2000


PREMA MERTZ
PRIMARY EXAMINER